UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,380	10/15/2003	Theresa Ditter	47563.0004	6318

57600 7590 08/17/2011

HOLLAND & HART
222 South Main Street, Suite 2200
P.O. Box 11583
Salt Lake City, UT 84110

EXAMINER	
BLATT, ERIC D	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
08/17/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,380	DITTER, THERESA	
	Examiner	Art Unit	
	ERIC BLATT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-23-2011 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-30 and 38-41are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (US 5,545,178) in view of Wahr et al. (US 2002/0183787) and Buckman et al. (US 2003/0176890).

Kensey discloses a tissue puncture closure device (Figures 1-5) comprising a carrier tube 88, a filament 42 attached to an anchor 38, a sealing plug 36 comprising a collagen sponge, and a locking apparatus comprising holding member 40 and knot 62 wherein said locking apparatus is separate from the filament, anchor, and sealing plug

and is arranged adjacent the sealing plug for compressing the sealing plug along the filament toward the anchor. Wahr discloses a similar sealing device (Figures 9-11 and 16) wherein a locking element 70 (Figure 16) is provided to urge an anchor 12 and a plug 14 toward one another along a filament 16. Wahr teaches that an alternate locking means may be provided to perform this function wherein the locking means comprises a ratchet mechanism. (Paragraph 72) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Kensey by providing the ratcheting locking mechanism 70 of Wahr since this was a known alternative to press a sealing plug against a puncture and its use would not have produced unexpected results.

With regard to the claimed ratchet structure, Wahr states only that the locking element 70 may acts as a ratchet mechanism, but does not provide a drawing showing detailed structure of this system. Buckman discloses a ratchet mechanism that functions similarly to that of Wahr wherein the structure of the mechanism is fully depicted. Buckman discloses a ratchet mechanism comprising a hub 28, an elongated track 18, a plurality of sloping teeth 20, and a shoulder stop for limiting movement of the hub (the flat side of each tooth acts as a shoulder stop preventing the locking hub from traveling backwards), and that the hub 28 comprises a nut having a flexible internal finger 32 wherein said finger comprises a notch or an external corner shaped to mate a surface of the plurality of sloping teeth. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus taught by Kensey and Wahr by providing the ratchet features taught by Buckman along a length

of the filament 42 since Wahr fails to detail the structure of the disclosed ratchet mechanism and the Buckman structure would have functioned well for the intended purpose. Examiner notes that the concept of providing a ratchet strap along a length of a filament was old and well known and that such a configuration would not have produced unexpected results. (See, e.g., US Patent No. 4,135,272 to Stephenson or US Patent No. 4,458,385 to Espinoza) Since the ratchet features are applied only along a portion of the filament where the holding member 40 is disposed, the ratchet mechanism terminates proximal of a distal end of the filament, and the pivotable connection of the anchor to the filament is maintained.

With regard to the recitations that the ratchet strap is separate from and attached to the filament, Wahr appears to suggest using the filament itself as a ratchet strap while Buckman discloses only a ratchet strap wherein said strap is not attached to a filament. When modifying the Kensey apparatus to use the ratcheting locking means disclosed in Buckman, one skilled in the art would have a choice between providing a separate ratchet strap (similar to the strap disclosed in Buckman) along a portion of the filament 42, or alternatively, to integrally form ratchet teeth along the filament 42 itself so as to form a ratchet strap that is integral with the filament 42. It would have been obvious to one of ordinary skill in the art to form the ratchet strap such that it comprises a separate element attached along a portion of the filament since it has been held that wherein two devices are differentiated only in that components of the devices are separable or integral, making those components either separable or integral does not patentably distinguish the devices. *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347,

349 (CCPA 1965), *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) By forming the ratchet track of the modified Kensey apparatus such that it is a separate element disposed along the filament 42, the device will comprise a first member (the ratchet track) that maintains a fixed position relative to the filament, and a second member (the hub) that is movable along the filament relative to and in contact with the first member.

The teeth of the modified device would comprise the claimed first member that maintains a fixed position relative to the filament, and the hub of the modified device would comprise the claimed second member that is movable along the filament relative to the first member.

Regarding claims 38-41, the modified device as set forth above comprises a filament having a ratchet strap along a portion of its length where the locking hub is configured to lock to the strap. The anchor 38 is capable of pivoting relative to the filament. The filament comprises a single strand that extends through the sealing plug, and a distal end of said filament is attached to the anchor at points 54 and 56. Regarding the recitation that the first member (the ratchet strap) is molded around the filament, the ratchet strap of the modified device is attached to a portion of the filament. It would have been obvious to mold these elements together since the attachment means is a matter of design choice. (See Paragraph 25 of Applicant's specification which states that the strap may be molded around the filament or, alternatively, the strap may include a hole through which the suture extends to fasten said elements together. Paragraph 25 continues, explaining that it will be understood by those of skill

in the art that other fastening mechanisms between these elements may be used.) With regard to the location of the ratchet track along the filament, it would have been obvious to located the track along the segment of the filament where the holding member 40 is to be attached. This position comprises a location that is spaced between the distal and proximal ends of the filament.

Response to Arguments

Applicant's arguments filed 12-7-2010 have been fully considered but they are not persuasive.

Applicant notes that none of Kensey, Wahr and Buckman individually disclose a ratchet strap that is separate from and attatched to a filament. Examiner acknowledges Applicant's position that each of these references individually fail to meet all claim recitations, but maintains that the combination of references fairly teaches the apparatus as claimed.

Applicant argues that there would be no motivation for one of skill in the art to form ratchet teeth in the filament 42 of Kensey would cause significant structural degradation to the filament. This statement appears to be speculative. Further, it seems plausible that one having ordinary skill in the art could select a filament that is capable of being engineered to have structural features along a portion of its length. Applicant further argues that this modification would hinder the ability of the filament to slide through the sealing plug and the anchor. Again, this argument appears to rely on

speculation, and even assuming this assertion were true, it is unclear how this sliding function might be critical to the performance of the device.

Applicant additionally argues that the filament 42 of Kensey comprises two strands, and that in order to attach a ratchet strap such as the one disclosed in Buckman to the filament of Kensey would require one of skill in the art to replace the 'two strands' and the holding member 40 with the ratchet components disclosed in Buckman. Examiner respectfully disagrees with this characterization. First, the Kensey filament comprises a single strand that doubles back at its distal end to form a knot that applies tension to the holding member 40. In replacing this connection means between the filament and the holding member with a ratchet mechanism as taught by Wahr and Buckman, there would be no need for the filament to double back. Additionally, the rejection as set forth above does not rely on replacing the filament with a ratchet track. Instead, a ratchet portion having the features taught by Buckman would be provided along a portion of the length of the filament where the holding member 40 is disposed. Examiner points to US Patent No. 4,135,272 to Stephenson and US Patent No. 4,458,385 to Espinoza as evidence that providing a ratchet portion along a length of a filament was well known. Examiner also notes that providing such a ratchet portion would not alter the pivotable connection between the filament and the anchor of Kensey.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EXAMINER whose telephone number is (571)272-9735. The examiner can normally be reached Monday to Friday from 10 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, SPE, at (571) 272-4697***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov**.**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. B./
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 3734